

## **REMARKS**

Reconsideration of the present application, as amended, is respectfully requested, in view of the remarks that follow, taken together with the attached Declarations listed below:

- (1) a Declaration of Garret D. Cawthon Under 37 C.F.R. §1.132,
- (2) a Declaration of Dean O. Harper Under 37 C.F.R. §1.132, and
- (3) a Declaration of Shishir Shah Under 37 C.F.R. §1.132.

This application, as amended, includes claims 39-53, 57-60 and 74-86, pending and under consideration.

In the Office Action mailed November 30, 2005, claims 39-60 stand rejected. Applicant submits that the claims, as amended herein, are in condition for allowance for the reasons set forth herein, and taken together with the Declarations attached hereto.

### **Remarks Regarding Evidentiary Effect of Rule 132 Declarations**

In the outstanding Office Action, the Examiner states that:

The declaration under 37 CFR 1.132 filed 8/16/05 has been considered but is insufficient to overcome the rejections...because: the Applicant has not presented any experimental data in support of her [sic] opinion. Due to the absence of tests comparing Applicant's compositions with those of the closest prior art and apparent self-interest of the declarant, the declaration constitutes self-serving opinion testimony, which is entitled to little weight. (Office Action, Page 9) (emphasis added).

In reply, Applicant submits that both of the two reasons supplied by the Examiner in the above-quoted statement for discounting the evidentiary effect of the prior Declaration (underlined) are now moot, because (1) the three Declarations submitted herewith provide experimental data comparing Applicant's compositions with that of the closest prior art, and (2) pertinent evidence supporting the patentability of the pending claims, as amended, is provided in the form of declarations of independent and disinterested third

parties, who have no ownership or financial interest in the present invention. As such, Applicant submits that the evidence set forth in these Declarations, which is uncontroverted in the record, is entitled to great weight.

#### **Remarks Regarding Claim Amendments**

Upon entry of the amendments to independent claims 39, 58 and 59 that are presented herein, Applicant has restricted the subject matter of the pending claims, and thus the subject matter for which patent protection is sought, to methods for spray delivery of diaper rash treatment compositions without the use of propellant gases entrained in the compositions (i.e., using non-aerosol delivery systems). These amendments are made without prejudice to the pursuit of patent protection for additional subject matter at a later time in this or a continuing patent application, but rather to expedite the allowance of this application by focusing the claims upon an aspect of the invention that is significantly distinct from the references of record and patentable over the prior art. While the use of entrained propellant gases is contemplated by other aspects of the present invention, the distinctions between aerosol and non-aerosol aspects of the invention are significant, and the amendments limiting the scope of the pending claims to delivery systems in which propellant gases are not released with the treatment composition are submitted for the purpose of expediting the allowance of this application. These amendments clarify distinctions between the prior art of record and the non-aerosol aspects of the invention, and thereby simplify and clarify the reasons that the claimed invention is patentable.

Furthermore, the use of propellant gases entrained in a diaper rash composition to achieve spraying gives rise to significant disadvantages. For example, a propellant gas mechanism produces a spray that feels cold, sometimes extremely cold, as the gas expands following its exit from the container through an actuator. This cold sensation can cause extreme discomfort when such a mechanism is used to spray a diaper rash composition onto the highly sensitive skin of the diaper area. In addition, the use of a

device at or near the sensitive diaper area that contains a gas under high pressure, kept from release only by an actuator is undesirable for multiple additional reasons. For example, there is always a chance that the high pressure gas could accidentally escape in an uncontrolled manner and perforate a bowel. Furthermore, products containing gas under pressure are more dangerous to transport, propellant gases are typically flammable, and propellant gases are environmental pollutants. Many propellant gases have been shown to deplete the ozone layer.

In view of the above, it is clear that there are significant detriments associated with the use of entrained propellant gases for the delivery of a diaper rash treatment composition. The very fact that such products have been proposed in the prior art, notwithstanding the significant disadvantages thereof, supports Applicant's position that the invention claimed in the present application, as amended, which provides a manner of achieving atomizing spray delivery of a diaper rash composition without having propellant gases entrained therein, is not obvious over the prior art. Indeed, the fact that the need or desire for a spray-on diaper rash treatment systems resulted in the development by others of inferior aerosol delivery systems supports Applicant's contention that the invention claimed in the present application is not obvious. The significant superiority of methods and systems that achieve atomizing spray delivery without entrained propellant gases, as described and claimed in the present application, are patently non-obvious over the cited prior art, and the present invention constitutes a significant advance in this field. Because the delivery of a diaper rash composition using a spray delivery mechanism is desirable for many reasons, and the use of propellant gases entrained in a diaper rash treatment composition is undesirable for many reasons, Applicant submits that the long span of time between the first suggestion of aerosol delivery systems for diaper rash treatment compositions to the filing of the present application (more than 25 years) is strong evidence that the present invention would not have been obvious to a person of ordinary skill in the art. Applicant therefore submits that it would not have been obvious to make and use methods, systems and compositions

recited in the present claims, as amended, which do not use propellant gases entrained in a diaper rash treatment composition, and that the proposals in the prior art of aerosol systems using entrained propellant gases supports this contention, as discussed further below.

Applicant has also made a few minor amendments to improve the clarity of the pending claims, and has requested entry of new claims 74-86, each of which is supported by the specification, and introduces no new matter into the application.

#### **Remarks Regarding Rejection of Claims 39-58 Under 35 U.S.C. §112**

Claims 39-58 are rejected in the outstanding Office Action under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In support of this rejection, the Examiner points to the words “calendula,” “chamomile” and “comfrey,” and states that, “It is unclear whether the Applicant intended to claim extracts of said plants, fresh plants, dried plants or essential oils of said plants or any other plant material(s).” (Office Action, Page 2-3). In reply, claims 39, 51 and 58 are amended to insert the word “extract” after each occurrence of the words “calendula,” “chamomile” and “comfrey” in the claims. Support for this amendment is found in the specification, for example at page 19, lines 19-21 (of original application) and page 20, lines 10-11.

#### **Remarks Regarding Rejections of Claims Under 35 U.S.C. §103(a)**

In the outstanding Action, the Examiner has withdrawn multiple grounds of rejection that were asserted in the prior Office Actions in this case, but has re-asserted one rejection of certain claims over a combination of references that was asserted in the prior Actions. In particular, claims 39-50 and 54-60 are rejected in the outstanding Action under 35 U.S.C. §103(a), as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502). Each of the alternative combinations is addressed below.

Applicant again submits that the pending claims are allowable over the cited references, and in support of the remarks set forth herein, Applicant submits herewith three additional Rule 132 declarations, namely, a Declaration of Garret D. Cawthon Under 37 C.F.R. §1.132 (hereafter “Cawthon Declaration”), a Declaration of Dean O. Harper Under 37 C.F.R. §1.132 (hereafter “Harper Declaration”) and a Declaration of Shishir Shah Under 37 C.F.R. §1.132 (hereafter “Shah Declaration”), to provide evidence in the record bearing on the patentability of the pending claims. Applicant submits that Dr. Dean Harper and Dr. Shishir Shah have no personal stake or interest in the present patent application or the underlying invention, and thus the Harper Declaration and the Shah Declaration cannot be found to constitute self-serving opinion testimony. In addition, the Cawthon Declaration presents data produced by objective testing that compared Applicant’s compositions with the composition described in what is considered to be the closest prior art. As such, Applicant submits that the Harper Declaration, the Shah Declaration and the Cawthon Declaration are entitled to great weight, and respectfully submits that the assertions therein, which are uncontroverted in the record of this case, must be accepted as persuasive evidence and *prima facie* proof of the facts asserted therein. In view of the remarks herein and the enclosed Declarations, Applicant respectfully submits that the pending claims, as amended, are in condition for allowance, and respectfully requests withdrawal of the rejections asserted in the outstanding Action.

#### **Remarks Regarding the Asserted Adams/Moss/Mulder Combination**

With respect to the rejection of claims under 35 U.S.C. §103(a), as being unpatentable over Adams et al. in view of Moss and Mulder, the rationale for this rejection is based upon the statement in the Action at page 3 that, “The recitation of viscosity that is ‘sufficiently low to allow the composition to be atomized’ is inherent in the [Adams et al. reference, which describes diaper rash aerosol composition containing about 70% of water, jojoba oil and macadamia oil] because the reference teaches compositions in the form of aerosols.” The secondary references (Moss and Mulder) are then combined with the Adams et al. reference on the assertion that they disclose various ingredients that could be

used in a diaper rash treatment composition. For example, the Examiner asserts that, “it would have been obvious to a person of ordinary skill in the art to modify the aerosol diaper rash compositions of Adams et al. such that to use [sic] zinc oxide for its art-recognized purpose.” The Examiner also states that, “it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of either Adams et al. [sic] such that to use cod liver oil, lanolin and petrolatum.”

In traversal of this rejection, Applicant submits that the invention recited in the present claims, as amended, is not obvious over this combination of references at least because the primary reference, Adams et al., only describes aerosol compositions that uses propellant gases entrained therein for delivery of the composition. Aerosol compositions containing propellant gases are not encompassed within the pending claims, as amended, and are fundamentally different than compositions encompassed by the pending claims, as amended. Thus, even if the references were to be combined as asserted by the Examiner, Applicant submits that the resulting combination does not read on or suggest the invention recited in the pending claims because the asserted combination would result in an aerosol composition delivered using propellant gases entrained therein. A person of ordinary skill in the art would have had no expectation that a composition having the physical properties described and claimed in the present application could be successfully made and delivered via an atomizing spray delivery mechanism without having propellant gases entrained therein.

When considering the question of whether a person of ordinary skill in the art would have been motivated to modify the teachings of the references of record in a manner that would be necessary to arrive at the invention claimed in the present application, as amended, it is important to remain focused on the physical properties of the compositions recited in the pending claims, i.e., to note that the pending claims relate to compositions that can be “atomized upon passage through the atomizing spray dispenser,” that do “not run off of the skin treatment area,” and that are propelled “toward the skin treatment area

substantially free from propellant gases.” (emphasis added). The claims exclude propellant-based aerosol delivery mechanisms that require propellant gases entrained in the composition, and Applicant submits that the rheological properties necessary to provide a spray dispensation system capable of atomizing a diaper rash treatment composition without having propellant gases entrained therein, while also providing for retention of the composition on the skin treatment area after delivery, are not taught, described or suggested in the cited references, nor are these features exhibited by the compositions described therein. Furthermore, a person of ordinary skill in the art would not have derived any motivation or suggestion to modify any composition or system as described in any of the references of record as would be necessary to arrive at the present invention. The rheological properties of compositions of the type described and claimed in the present application are complex, and a person of ordinary skill in the art therefore would have had no reasonable expectation, based upon the art of record, that any particular formulation of a diaper rash treatment composition could be produced that would have the properties described and claimed in the present application. Support for these contentions are found in the enclosed Declarations, as discussed further below.

Systems involving treatment compositions having propellant gases entrained therein are significantly different than systems that deliver compositions without having propellant gases entrained therein. As stated in the Shah Declaration, the concept of spraying a composition using propellant gas-based aerosol technology is significantly different than spraying a viscous composition using non-aerosol atomizing spray mechanisms. (Shah Declaration, Paragraph 4). As stated in the Harper Declaration, the invention claimed in the present application by Dr. Cawthon is significantly different than the composition described in Adams, Gebhart & Huffstetler because it does not involve diaper rash treatment compositions having propellant gases entrained therein. (Harper Declaration, Paragraph 5). In a propellant-based spray formulation, the propellant helps dilute the formulation in a fluid (the gas) so that a thicker, more viscous, composition once entrained in a gas, can be sprayed. In addition, the elevated pressure of the propellant helps push the

materials through the actuator, which also allows for compositions of higher viscosity to be sprayed through a nozzle. In these references, propellants are key in achieving sprayability. (Harper Declaration, Paragraph 5). In fact, it is noteworthy that the formulations described in Adams as being a lotion and a spray, respectively, are actually made of essentially the same ingredients in the same proportions with the only exception being that the “spray” formulation has a propellant gas entrained therein. Indeed, the inclusion of such a propellant gas is necessary to spray a composition of lotion-like consistency. In contrast, the invention described and claimed by Dr. Cawthon in the present application involves compositions having physical properties that provide good sprayability and also good resistance to run-off after being sprayed, all without having a propellant gas entrained therein. Because both the Adams et al. reference and the Gebhart et al. reference describe sprayable compositions of only the aerosol type (i.e., compositions with propellant gases entrained therein), those references cannot properly be found to be suggestive of methods and compositions encompassed by the present application which do not have propellant gases entrained therein. (Shah Declaration, Paragraph 4).

It would not have occurred to a person of ordinary skill in the art in view of the prior art to prepare a diaper rash treatment composition that is sprayable and has rheological properties suitable to prevent run-off upon being sprayed onto a skin treatment area, without having a propellant gas entrained therein, because the rheological properties that would be required to achieve this functionality are complex, and seemingly inconsistent, and the skilled artisan would not have been able to envision a formulation that would have the required properties. The rheological properties of non-Newtonian systems are complex and a simple Brookfield viscosity measurement cannot completely describe the rheology. (Cawthon Declaration, Paragraph 11). As seen in the enclosed Harper Declaration, Dr. Harper, who is an expert in the field of rheology, is of the opinion that it would not be obvious to a person of ordinary skill in the art to make a non-aerosol spray-on, run-off resistance product by simply adding ingredients from one formulation into another formulation or diluting a viscous paste/ointment with a solvent. (Harper



Declaration, Paragraph 3). More complex behavior is needed to make a liquid that is sprayable using non-aerosol mechanisms, i.e., without the use of propellant gases entrained therein, and that does not run off of the skin treatment area. (Harper Declaration, Paragraph 3). The two goals have conflicting properties. (Harper Declaration, Paragraph 3). Notwithstanding this, the present invention involves the discovery that formulations can be made that have the necessary rheological properties to achieve this result. (Harper Declaration, Paragraph 3). The compositions described and claimed in the present patent application exhibit “time-dependent, shear-thinning, plastic” rheology. (Harper Declaration, Paragraph 15).

Of all of the reference cited in the present case, only Mulder purports to describe a composition that is sprayable, but is silent as to the use of propellant gases (See Table 1 at Column 5 of Mulder). The description in the Mulder reference of the composition set forth in Table 1, however, also suggests that this composition would not be able to form a coating that “does not run off of the skin treatment area,” as recited in Dr. Cawthon’s pending claims. Specifically, Mulder states that:

The mechanical action of the spray liquid permits a complete flushing of the wound site to soften and rinse away debris from the wound. (Mulder, Column 5, line 65 to Column 6, line 1).

In view of the suggestions of sprayability and run-off after spraying that would be required to provide the “rinsing” function discussed above, a person of ordinary skill in the art would not expect this composition to have the properties claimed in the present application (i.e., sprayability and run-off resistance). Moreover, upon considering the list of ingredients set forth at Column 5 in Table 1 of Mulder, a person skilled in the art would expect that the composition would not be sprayable at all absent propellant gases entrained therein. Indeed, Dr. Cawthon’s declaration, which is submitted herewith, sets forth the results of experimental testing of the composition described in Table 1 of Mulder, showing

that this composition in fact does not have the properties described and claimed in the present patent application. (Cawthon Declaration, Paragraph 15).

Applicant has now, for the purpose of conducting objective testing, formulated compositions according to the formula set forth in Table 1 at Column 5 of the Mulder reference, which is considered to be the “closest prior art” of record based upon the statements made therein. Extensive testing of this composition and of multiple compositions described and claimed in the present application has been completed. As discussed further below, Applicant has determined that the composition described in Mulder does not have the properties described and claimed in the present application and therefore does not teach or suggest the invention claimed in the present application, as amended. (Cawthon Declaration, Paragraph 4). In the tests reported in the attached Cawthon Declaration, six compositions were tested for sprayability and the degree of run-off resistance, which are properties recited in the claims recited in the present application, as amended. (Cawthon Declaration, Paragraph 11). The six Formulations tested in the reported in the attached Cawthon Declaration were the following:

Formulation #1 is detailed in the present application at page 18 lines 12-16

Formulation #2 is detailed in the present application at page 19 lines 13-16

Formulation #3 is detailed in the present application at page 21 lines 5-9

Formulation #4 is a product encompassed by the pending claims

Formulation #5 is a product encompassed by the pending claims

Formulation #6 is the composition set forth in Table 1 at Column 5 of Mulder's US Patent 5,536,502

With respect to the sprayability of the respective formulations, the sprayability standard used in the tests requires that the material can be atomized and dispensed in a spray form at room temperature using a pump spray mechanism (i.e., without using propellant gases). (Cawthon Declaration, Paragraph 12). Each of Formulation #1 to Formulation #5 passed the sprayability test; however, Formulation #6 (the Mulder

formulation) did not. (Cawthon Declaration, Paragraph 15). The Mulder composition had a consistency that resembled a thick paste at room temperature and that resembled pancake batter at a relatively high temperature (50°C). The liquid was able to be sprayed while at 50°C, but not at room temperature, and thereby failed the sprayability test. The consistency of the formula is typical with one having such high levels of “thick” ingredients: 10% Mineral Oil Gel, 13.50% Glycerine, and 9.50% Lanolin Oil. An emulsion base further increases the viscosity. (Cawthon Declaration, Paragraph 15).

A person of ordinary skill in the art would not have derived any motivation or suggestion to modify any composition or system as described in any of the references of record as would be necessary to arrive at the present invention. As stated above, with respect to the Adams et al. reference, which is relied upon in the Action as teaching “a diaper rash aerosol composition containing about 70% of water, jojoba oil and macadamia oil,” the pending claims, as amended, do not encompass aerosol compositions having propellant gases entrained therein. Thus, even if the aerosol composition described in Adams et al. is modified to include ingredients set forth in Moss and Mulder as proposed in the Action, Applicant submits that the resulting combination still does not produce the present invention, because all elements recited in the pending claims, as amended, are not provided by the combination.

In determining what a person of ordinary skill in the art would be motivated to do upon consideration of the cited art, it is imperative to consider that such a skilled person would understand the difference between oily, pasty, hydrophobic barrier-type ingredients and other types of ingredients that would reduce the barrier functionality of a composition. It is therefore inappropriate to focus solely upon the question of whether a given ingredient is of the type that a person of ordinary skill in the art would consider including in a diaper rash treatment composition, without regard to the physical properties of the ingredient, the desired effect of the ingredient in the composition, and, indeed, without regard to the important fact that a person of ordinary skill in the art would have found no motivation in

the prior art to deliver a barrier-type diaper rash composition via an atomizing spray dispenser without propellant gases entrained therein.

Simply combining ingredients that are considered to be acceptable for inclusion in a diaper rash treatment composition is not sufficient to arrive at the present invention as recited in the pending claims, and the identification of all known ingredients that might be suitable for inclusion in a diaper rash composition would not have motivated or enabled a person of ordinary skill in the art to practice the present invention. (Shah Declaration, Paragraph 7). Indeed, a person of ordinary skill in the art at the time of the present application would not have believed that a composition could even be formulated to be capable of BOTH being applied to a skin treatment area via an atomizing spray dispenser in the absence of propellant gases entrained therein AND providing a suitable barrier functionality for the treatment of diaper rash. (Shah Declaration, Paragraph 7). These characteristics are at odds with one another, and a person of ordinary skill in the art would not have believed that such a formulation could be developed. (Shah Declaration, Paragraph 7). There is certainly no description or suggestion in the cited references of a composition that has both of these capabilities. Absent the motivation provided by the present invention, a person of ordinary skill in the art would not have combined ingredients from the respective references in a manner that would be necessary to practice the present invention. (Shah Declaration, Paragraph 7).

Given that simply selecting ingredients from the various references itself is not sufficient to arrive at the present invention, a person of ordinary skill in the art would need to find further motivation to combine suitable ingredients in a suitable manner to provide a composition that has physical properties that “allow the composition to be atomized upon passage through the atomizing spray dispenser [without a propellant gas]” and such that “the coating does not run off of the skin treatment area.” The cited references do not supply the motivation to combine ingredients in this manner. (Shah Declaration, Paragraph 7). There is simply no teaching or suggestion of a composition in the cited references that has the combination of physical properties discussed herein.

In addition to the above, the present invention proceeds contrary to the accepted wisdom that existed at the time the application was filed. As stated in MPEP §2145, “The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. In re Hedges, 783 F.2d 1038, 228 USPQ 685 (Fed.Cir. 1986).” To accurately understand the suggestive effect of the cited references, and to fully appreciate what the cited references would suggest to one skilled in the art at the time of the invention, it is important to consider the art as a whole at the time the invention was made, including trends and beliefs in the field of diaper rash treatment and the perspective of a person skilled in the art. A person of ordinary skill in the art at the time of the present invention would have understood that all diaper rash treatment products fall into one or both of the following two categories: “protective barrier” compositions and “active agent delivery” compositions. (Shah Declaration, Paragraph 8). Of course, a given product could belong in both categories, i.e., a protective barrier composition could also include one or more active agents. However, one important distinction between these two categories of diaper rash treatment products is the following: while active agent delivery compositions could take a wide variety of physical forms (i.e., aqueous liquids, emulsions, creams, ointments, pastes, powders or other solids), the physical form of protective barrier compositions was and is relatively uniform: a highly viscous, typically hydrophobic, paste, ointment or cream. (Shah Declaration, Paragraph 8). Such highly viscous compositions were believed to be necessary to provide a suitable protective barrier product. (Shah Declaration, Paragraph 8).

Significant efforts have been made in the prior art, and significant resources have been devoted to efforts to identify the precise cause or causes of diaper rash, with the belief that this would enable the development of formulations that include active ingredients selected to address the cause more directly. (Shah Declaration, Paragraph 9). Even in view of significant efforts to identify the specific cause of diaper rash, it was generally believed at the time the present application was filed, and is generally believed at this time, that the most important feature of a diaper rash treatment composition is its ability to provide a

physical, non-soluble barrier between urine and/or feces and the underlying skin. (Shah Declaration, Paragraph 9). As stated at page 3 of the present application:

Because the suspected agents of diaper rash ... all possess diverse properties and require varied therapies, conventional methods of treatment for diaper dermatitis have been directed toward a straightforward attempt to minimize the contact of the skin with the feces or urine present in a soiled diaper. An artificial barrier is usually provided between the skin and the body waste to accomplish this... [Because] the exact components of urine or feces which act as factors or cofactors contributing to diaper dermatitis have never been precisely identified, the most effective method of treating diaper rash to date has been the artificial barrier.

In keeping with the trend of providing an artificial barrier in conventional treatments of diaper rash, a wide variety of highly viscous pastes, ointments and creams have been developed to be applied to skin in an effort to provide a suitable barrier to prevent skin contact with urine and/or fecal matter. (Shah Declaration, Paragraph 10). Because urine is an aqueous liquid, and fecal matter sometimes also has a high water content, it has been long understood and widely accepted that, to be effective, the paste, ointment or cream should be formulated as a highly viscous, hydrophobic preparation. (Shah Declaration, Paragraph 10).

In view of this background, it is apparent that the present invention proceeds contrary to the accepted wisdom that existed at the time the application was filed. A person of ordinary skill in the art at the time of the present invention would have understood the limitations on the physical characteristics of ingredients in a barrier composition, and would not have been motivated to add ingredients into a barrier formulation that would reduce the viscosity or hydrophobicity thereof, much less try to formulate a barrier composition that could be passed through an atomizing spray delivery mechanism. (Shah Declaration, Paragraph 11). Similarly, a person of ordinary skill in the art would have had no motivation to pluck ingredients from a "protective barrier" composition for inclusion in a liquid "active agent delivery" composition. (Shah Declaration, Paragraph 11). Limited attempts have been made to deliver diaper rash treatment compositions using aerosol technology, but these attempts have not met with success.

A person of ordinary skill in the art at the time of the application would not have modified a low viscosity, non-aerosol, sprayable composition by adding high viscosity barrier-type ingredients at a level necessary to provide a composition having the physical properties described and claimed in the present application because he or she would have expected the operability (i.e., sprayability) of the spray system to be degraded to a point where the modification would not be desirable. (Shah Declaration, Paragraph 12). He or she therefore would have had no reasonable expectation of success, and would not have been motivated to even attempt to make such modifications. (Shah Declaration, Paragraph 12).

Similarly, but from a different perspective, a person of ordinary skill in the art at the time of the application would not have modified a highly viscous, hydrophobic barrier composition by adding viscosity-reducing or hydrophobicity-reducing ingredients in amounts necessary to make a composition suitable for passage through an atomizing spray dispenser without having propellant gases entrained therein, as described and claimed in the present application, because he or she would have expected the operability (i.e., barrier functionality) of the barrier system to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success, and would not have been motivated to even attempt to make such modifications. (Shah Declaration, Paragraph 12). It is believed that the prior art is devoid of any information suggesting that the combination of properties recited in the pending claims would be achievable in a composition as recited in the pending claims, as amended. A person of ordinary skill in the art at the time of this application would not have expected any composition having a viscosity “sufficiently high that the coating does not run off of the skin treatment area” as recited in the claims, as amended, also to be suitable for delivery through an atomizing spray dispenser without having propellant gases entrained therein, as also recited in the pending claims, as amended. (Shah Declaration, Paragraph 12).

In view of the above, Applicant submits that neither Adams et al. nor any other reference of record in this case, would be understood by a person of ordinary skill in the art to provide any teaching, suggestion or motivation to modify their teachings in a manner that

would lead to the present invention. (Shah Declaration, Paragraph 16). A person of ordinary skill in the art would find no motivation in the cited references to use a highly viscous paste, ointment or cream, or the ingredients thereof, in a non-aerosol spray system. (Shah Declaration, Paragraph 16). A person of ordinary skill in the art would not have modified a highly viscous paste, ointment or cream protective barrier formulation to make it sprayable, and would not have selected ingredients thereof for inclusion in a spray-on diaper rash composition. (Shah Declaration, Paragraph 16). Similarly, but from another perspective, a person of ordinary skill in the art would not have modified a low viscosity sprayable composition by adding high viscosity barrier-type ingredients at a level necessary to provide a barrier-type composition, and would not have selected ingredients thereof for inclusion in a barrier-type ointment. (Shah Declaration, Paragraph 16).

In addition to the above, the nonobviousness of the claimed invention is supported by the fact that multiple embodiments of the invention (see, for example, formulations 4 and 5 above) have been recognized by experts in the relevant field as being a significant advance over the prior art. In particular, the present invention has been recognized by the medical community for its unique technology and performance. For example, products encompassed by the present invention that have been developed and marketed (available for purchase at [www.touchlesscare.com](http://www.touchlesscare.com)) won the top vote award at the MedAssets' New Technology Fair in October 2005, at which 47 preselected high-tech healthcare companies presented their new products. MedAssets is the third largest Group Purchasing Organization in the US, and has contractual relationships with about one-fourth of all US hospitals. The judges were composed of technical specialists in the various disciplines, including skin and wound care specialists. The grading criteria (based on a 4.00 scale) used by the judges were as follows, and the scores of the inventive compositions are set forth in parentheses:

Vendor's technology...

- is new and can be considered "breakthrough" technology (4.00).
- will have a significant impact on improving patient care (3.93).
- will have a significant impact on improving labor efficiency (3.91).



- will have a significant impact on improving cost efficiency (3.84).
- will benefit the MedAssets' contract portfolio (3.81).

Overall Score: 3.90 (#1 out of 47 companies)

Attached hereto is a copy of the letter reporting the above-described result and detailing this information. In addition, spray-on products that embody the invention described and claimed in the present application were recently selected as a finalist for the Henry Vogt award for excellence in product innovation. (Cawthon Declaration, Paragraph 17).

Applicant also submits that the Mulder reference is nonanalogous art. As stated in MPEP §2141.01(a), "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." Mulder cannot be relied upon as a basis for rejection of claims in the present application because it does not satisfy either of these two requirements.

Mulder is not in the field of applicant's endeavor. As stated at page 1 of the present application, "The present invention relates to methods, compositions and systems for the prevention and treatment of diaper rash." In contrast, Mulder states at Column 1, lines 7-9 that, "The present invention pertains to the field of topical ointments and, more particularly, to products that are used for the treatment of superficial lesions including skin tears." It is stated in the Office Action that Mulder is in the same field of endeavor as the present invention "because both inventions are concerned with skin healing." Applicant respectfully disagrees with this statement. It is important to recognize that the field of endeavor involving treating skin tear wounds is significantly different than the field of endeavor involving treatment and prevention of diaper rash. (Shah Declaration, Paragraph 14). A person of ordinary skill in the field of skin tear wounds would understand the importance of giving careful attention to cleaning any and all debris and infectious agents from the wound, applying medicines to the wound, keeping the wound clean, and ensuring that an unrestricted amount of oxygen is able to reach the wound to allow proper healing. (Shah Declaration, Paragraph 14). With respect to the latter, a person of ordinary skill in the field of skin tear treatment would readily understand that a barrier-type composition

such as those discussed in the present application, should never be applied over a skin tear wound. (Shah Declaration, Paragraph 14). Numerous studies have shown that the proper healing of skin-breaking wounds is prevented by moisture barrier-type, or “occlusive” products, suppress recovery and reduce the epidermal proliferative response to the wound, while semipermeable, or “breathable,” materials do not slow recovery and allow for normal cellular respiration. (Shah Declaration, Paragraph 14). Thus, a barrier-type composition, or “occlusive product,” as described and claimed in the present application simply should not be used in the field of wound care. (Shah Declaration, Paragraph 14). In contrast, the field of diaper rash treatment, as discussed in detail herein, involves the placement of a robust and impermeable (non-breathable) barrier over an area of skin having, or at risk of experiencing, diaper rash. A barrier composition of this type would be totally unsuitable for placement on an open wound. Thus, barrier-type diaper rash treatment compositions should never be considered desirable for use in connection with a skin tear, and the two are properly considered different fields of endeavor. (Shah Declaration, Paragraph 14).

Mulder is also not reasonably pertinent to the particular problem with which the inventor was concerned. In the development of the present invention, the particular problem with which the inventor was concerned was that:

products currently available for the treatment of diaper rash...are very viscous and messy to administer to the skin. Such products require that the person applying the product spread the product by rubbing the same into or over the skin. While this requirement is typically acceptable in the case of a parent applying the product to the skin of an infant child, it is a drawback where a caregiver is in charge of providing such a treatment to multiple persons, especially multiple incontinent adults. The application of the product is messy and awkward because the product is difficult to wash off of ones hand due to its oily, hydrophobic nature. Additionally, the caregiver must first use one set of gloves to clean the patient, and then use another set of gloves to apply the ointment or lotion. This results in wasted time and resources.

(Specification, Page 5, lines 3-13). Mulder is not reasonably pertinent to this problem relating to the mess and inefficiency of applying an oily, hydrophobic ointment to a skin

treatment area. (Shah Declaration, Paragraph 15). Rather, Mulder is focused upon addressing the “need for a non-irritating, topical ointment or medicament that is specifically designed to promote the reepithelialization of skin tears.” (Mulder, Column 2, lines 18-20). This is not reasonably pertinent to the problem with which the present inventor was concerned because a product capable of promoting the reepithelialization of skin tears would not be pertinent to the problem of the mess and inefficiency of applying an oily, hydrophobic diaper rash ointment to a skin treatment area. (Shah Declaration, Paragraph 15). Furthermore, an oily, hydrophobic barrier-type diaper rash composition should never be used for treating skin tears, because a barrier composition would cause a significant impediment to wound healing. (Shah Declaration, Paragraph 15). Indeed, the compositions described by Mulder are designed around the concept of washing/flushing the wound site, and thus only a small proportion of the composition applied to the wound would even remain after the flushing was completed. (Shah Declaration, Paragraph 15). This is a fundamentally different purpose than the purpose of a barrier-type diaper rash composition, which functions optimally by being retained on the skin in its entirety. (Shah Declaration, Paragraph 15). Thus, the properties that would be desirable in the respective types of compositions are significantly different. (Shah Declaration, Paragraph 15). As such, Mulder is nonanalogous art because it is not in the field of applicant's endeavor or reasonably pertinent to the particular problem with which the inventor was concerned.

In view of the above, Applicant respectfully submits that the rejection of claims as being unpatentable over Adams et al. in view of Mulder and Moss is overcome, and respectfully requests withdrawal of same.

Remarks Regarding the Asserted Gebhart/Moss/Mulder Combination

With respect to the rejection of claims under 35 U.S.C. §103(a), as being unpatentable over Gebhart et al. in view of Moss and Mulder, Applicant submits that this rejection is made on the same grounds as the Adams/Moss/Mulder rejection discussed above. The only difference is that Gebhart et al. is cited as disclosing an aerosol-based delivery system for treating skin irritations such as diaper rash, rather than Adams et al.

In traversal of this rejection, Applicant submits that the combination of the Gebhart et al. reference with the Moss and Mulder references does not support an obviousness rejection of the pending claims for the same reasons that the combination of Adams et al. with Moss and Mulder does not form the basis of a proper rejection, and that the claimed invention is not obvious over this combination of references because there is no teaching, suggestion or motivation to be found in the cited references or in the prior art as a whole to modify the cited references in a manner that would be necessary to arrive at the present invention. (Shah Declaration, Paragraph 17). A person of ordinary skill in the art would find no motivation to combine the Gebhart et al. and Moss and Mulder references in the manner suggested in the Action for the same reasons that there is no motivation to combine the Adams et al. and Clark et al. references, discussed above, and that the combination of the disclosures therein, even if made, would not have resulted in the present invention because Gebhart et al. describes an aerosol delivery system. The undersigned therefore submits that the cited references do not teach or suggest a method as recited in the subject claims, as amended, and would not motivate a person of ordinary skill in the art to modify the references to arrive at the present invention. Withdrawal of this rejection is also respectfully requested.

Remarks Regarding the Asserted Adams/Gebhart/Moss/Mulder/Boussouira Combo

In the outstanding Office Action, claims 41-43, 59 and 60 are rejected under 35 U.S.C. §103(a), as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254) and Mulder (US 5,536,502), and further in view of Boussouira et al. (US 6,103,247). In traversal of this rejection, Applicant submits that the pending claims, as amended, are not obvious over these asserted combinations for the same reasons as set forth above, and that the Boussouira et al. reference also fails to provide any motivation to combine the references and fails to provide the missing features of the combination. (Shah Declaration, Paragraph 18). As such, Applicant submits that this rejection is also improper for at least the same reasons that the

rejection of claims over a combination of Adams et al. or Gebhart et al. and Moss and Mulder is improper.

Remarks Regarding the Asserted Adams/Gebhart/Neubourg Combination


In the outstanding Office Action, claims 39, 51 and 52 are rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Neubourg (WO 99/08649 as translated by US 6,423,323). In traversal of this rejection, Applicant submits that the pending claims, as amended, are not obvious over these asserted combinations for the same reasons as set forth above with respect to the rejection of claims based upon a combination of the Adams et al. or Gebhart et al. and Moss and Mulder references. In addition, the Neubourg reference is also centered on propellant gas systems, and is therefore distinct from the present invention for this reason also. As such, Applicant submits that this rejection is also improper for at least the same reasons that the rejection of claims over a combination of Adams et al. or Gebhart et al. and Moss and Mulder is improper. (Shah Declaration, Paragraph 18).

Applicant submits that, when properly considered, the only suggestion of the presently claimed invention is provided by the present application. One having ordinary skill in the art at the time of the invention would not have derived any motivation from the cited references to make modifications to the described compositions that would have been necessary to arrive at the invention as recited in the present claims, as amended. Applicant therefore respectfully submits that claims 39-60 and 74-86, as amended, are allowable over the cited references and request that the rejection of claims under 35 U.S.C. § 103(a) be withdrawn.

**Closing**

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 39-53, 57-60 and 74-86, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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RESPONSE TO OFFICE ACTION

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